



UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/621, 146 07/21/00 SUMIAN

C BJA 254A

HM12/0605

BOLESH J SKUTNIK PHD JD
515 SHAKER ROAD
EAST LONGMEADOW MA 01028

EXAMINER

DEWITTY, R

ART UNIT	PAPER NUMBER
----------	--------------

1616

DATE MAILED:

06/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Offic Action Summary	Application No.	Applicant(s)
	09/621,146	SUMIAN, CHRYSLAIN
	Examiner	Art Unit
	Robert M DeWitty	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 July 2000.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-19 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-19 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|--|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-19 are pending in the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1,2,10,11,12,14,15 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al.

Suzuki et al. (U.S. Pat. No. 4,292,299) teaches slow-releasing medical preparations to be administered to the wet mucous surface of the skin of men and animals. The preparation consists of two layers, an adhesive layer, and a non-adhesive layer, wherein said adhesive layer has adhesiveness to a wet mucous surface and has the property of swelling upon moistening (col. 2, lines 6-15). The property to swell upon moistening is necessary for the gradual release of the medicament contained within the preparation (col. 2, lines 38-42). A list of suitable polymers that can be used as the adhesive layer are shown in Table 1, column 6.

Thus, the above claims are anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 13, 16, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al., further in view of Schaefer et al.

As stated above, Suzuki et al. teaches slow-releasing medical preparations to be administered to the wet mucous surface of the skin of men and animals, wherein such preparations swell following application to the skin. However, Suzuki et al. does not teach using polymer microspheres.

Schaefer et al. (U.S. Pat. No. 5,292,512) teaches a pharmaceutical or cosmetic composition for topical application containing microspheres filled with active products. The microspheres are designed such that the spheres enter the follicle, wherein the active product they carry diffuses into the follicular canal and the surrounding tissues (col. 1, lines 62-66). The microspheres taught by Schaefer et al. can be made by using a polymer that swells, thereby creating the microspheres in gel form (col. 4, lines 65-67). The benefits of using Schaefer et al.'s invention is that due to the entry of the microspheres into the sebaceous follicles, the active product can be brought specifically to the target regions with no secondary effects on the skin regions surrounding the follicular channel (col. 2, lines 29-40), in comparison to topical applications which do not have the desired effectiveness because the epidermis forms a barrier (col. 1, lines 42-44).

Based on the art available at the time the invention was made, a method for applying microspheres, whereby said microspheres swell following application, would have been known to one with ordinary skill in the art. Further, it would have been known that the microspheres can contain pharmaceutical or chemical components. One with ordinary skill in the art would have been motivated to administer such drug enhanced, swelling, microspheres to penetrate the epidermis when applied because the effectiveness of the drug to the localized area would be much more so in comparison to topical-only applications.

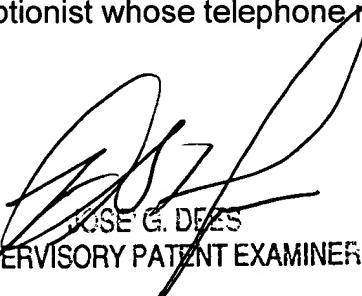
Thus, the invention is made obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned is 703-308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
June 3, 2001


JOSE G. DEES
SUPERVISORY PATENT EXAMINER

1616